



STATE OF TENNESSEE  
BUREAU OF TENNCARE  
DEPARTMENT OF FINANCE AND ADMINISTRATION  
729 CHURCH STREET  
NASHVILLE, TENNESSEE 37247-6501

## **The State of Tennessee, TennCare Bureau PHARMACY PARTICIPATION AGREEMENT For Ambulatory and Long Term Care Pharmacy Providers**

THIS AGREEMENT effective \_\_\_\_\_ is between the State of Tennessee, TennCare Bureau, Department of Finance and Administration (hereinafter referred to as TennCare) and \_\_\_\_\_ (hereafter referred to as Pharmacy).

WHEREAS, the State of Tennessee, TennCare Bureau is responsible for the financial, clinical and managerial aspects of the TennCare pharmacy program for TennCare/Medicare enrollees and behavioral health pharmacy services and the total pharmacy benefit for all TennCare enrollees after July 1, 2003, and;

WHEREAS, the Pharmacy is desirous to participate in contractual prescription filling activities under this TennCare program, and;

WHEREAS, the State of Tennessee, TennCare Bureau provides drug benefit programs to TennCare enrollees through arrangements with regional and statewide pharmacy networks; and,

WHEREAS, participating pharmacies are members of the TennCare Bureau's network, contractually bound to meet TennCare standards, including but not limited to, emergency services, compliance with the *Grier* Revised Consent Decree, maintenance and review of patient profiles, patient consultation and medication information and utilization review; and,

WHEREAS, the Pharmacy and TennCare desire to promote high standards of pharmaceutical care on a cost effective basis through drug utilization review activities.

### **SECTION 1 DEFINITIONS**

**Section 1.1: Definitions.** The following terms shall have the following meaning:

**Ambulatory Pharmacy:** A chain drug store or independent pharmacy or any other entity licensed by the Tennessee Board of Pharmacy, or an entity duly licensed by any State Pharmacy Board, to dispense prescriptions to outpatient clients in any ambulatory setting.

**Average Wholesale Price:** The average wholesale price (A.W.P.) for a pharmaceutical product as established in the First Data Bank price file and updated no less than twice monthly.

**Co-payment Charge or Co-insurance Charge:** The amount certain TennCare enrollees are required to pay for certain Pharmaceutical Services in accordance with the TennCare waiver.

**Customary Charge:** The reasonable, usual and customary fees charged by Pharmacy which do not exceed the fees Pharmacy would charge any other person regardless of whether the person is a TennCare enrollee.

**Deductible:** The annual amount of charges for Pharmaceutical Services and/or medical expenses as provided in the TennCare waiver that the TennCare enrollee is required to pay.

**Drug Formulary:** Prior to July 1, 2003, reimbursement for pharmacy services is limited to only those drugs covered by the TennCare Pharmacy Program for the all eligible TennCare/Medicare enrollees and all TennCare behavioral health pharmacy services for eligible TennCare enrollees. This TennCare program may utilize a negative drug formulary list. This is a list of drugs that are **NOT** covered by TennCare. The TennCare Bureau may develop this negative drug formulary list and make any changes subsequent to its implementation on or after July 1, 2000. Any changes to this negative drug formulary list will not take place until thirty (30) days after all affected providers are notified. A maintenance drug list and any over-the-counter (OTC) drugs covered by this program will be listed in a separate formulary. This negative drug formulary list, the maintenance drug list and the OTC list will be distributed to pharmacies and posted on the TennCare website ([www.tennessee.gov/tenncare](http://www.tennessee.gov/tenncare)). Coverage and reimbursement for legend, maintenance and OTC drugs by the TennCare program is contingent upon a prescription written by a licensed prescriber. OTC drugs that are required to be floor stock items in a long term care facility will not be covered for nursing home residents.

After July 1, 2003, following notice from TennCare, reimbursement for pharmacy services will be limited to the TennCare preferred drug list (PDL). This PDL will apply to all prescriptions for all TennCare enrollees. The PDL will be distributed to pharmacy providers and posted on the TennCare website ([www.tennessee.gov/tenncare](http://www.tennessee.gov/tenncare)).

**Long Term Care Facility:** A long-term care facility (nursing home) is a facility planned, staffed, and equipped to accommodate individuals who do not require the degree of care or treatment normally given by a hospital, but who are in need of a wide range of medical, nursing, pharmacy and related health and social services which are provided by appropriately licensed healthcare professionals.

**Long Term Care Pharmacy Provider:** Any entity licensed by the Tennessee Board of Pharmacy to dispense prescriptions to or for residents of long term care facilities (nursing homes).

**Maximum Allowable Cost Limit (MAC):** The list of pharmaceutical products that will be reimbursed at a generic product level established by TennCare. The MAC list includes, adjacent to each pharmaceutical product listed, the corresponding maximum allowable cost per unit that will be used in calculating the reimbursement by TennCare to Pharmacy. This list is subject to periodic review and modification by TennCare.

**Network:** The group of pharmacies participating in this TennCare program and subject to this agreement.

**Participating Pharmacy Provider Number:** Each Pharmacy which signs this agreement and all other necessary participating pharmacy provider application forms will always use their assigned NCPDP (formerly known as NABP) number when submitting pharmacy claims to TennCare. This number must accompany all claims for reimbursement and all correspondence or communication with the TennCare Bureau.

**Participating Pharmacy Provider Number:** Each Pharmacy which signs this agreement and all other necessary participating pharmacy provider application forms will always use their assigned NCPDP (also known as NABP) number when submitting pharmacy claims to TennCare. This number must accompany all claims for reimbursement and all correspondence or communication with the TennCare Bureau.

**Pharmaceutical Product:** A medication or a pharmaceutical product or device which has been prescribed for an eligible TennCare enrollee by an authorized prescriber.

**Pharmaceutical Service:** A pharmaceutical product or service provided to TennCare enrollees for outpatient administration or for administration in a long term care facility which is covered under this TennCare program and meets the criteria set forth in TennCare Pharmacy Manual.

**Preferred Drug List (PDL):** On July 1, 2003, TennCare will begin the implementation process of a single, statewide preferred drug list (PDL) that will replace the different drug formularies used by the TennCare managed care organizations (MCOs). The PDL will define the drug coverage for all TennCare enrollees. The PDL will be distributed to pharmacy providers and posted on the TennCare website ([www.tennessee.gov/tenncare](http://www.tennessee.gov/tenncare)).

**Prescriber:** A Doctor of Medicine or other health care professional who is duly licensed and qualified under the laws and jurisdiction of Tennessee in which Pharmaceutical Services are received and may in the usual course of his or her practice legally prescribe pharmaceutical products for TennCare enrollees.

**Prescription Order or Refill:** The authorization for the dispensing of a pharmaceutical product issued by a Prescriber who is duly licensed to make such authorization in the ordinary course of his or her professional practice.

**TennCare enrollees:** An individual who is properly enrolled for coverage under TennCare, including beneficiaries of the Medicare Program benefits administered by the Centers for Medicare and Medicaid Services ("CMS") division of the United States Department of Health and Human Services (also known as a TennCare enrollee or TennCare member).

**TennCare Pharmacy Manual:** A manual developed by TennCare which describes the administrative policies and procedures established by TennCare for participating pharmacies regarding their providing of Pharmaceutical Services to the TennCare enrollees described in this TennCare program. This manual is subject to periodic review and modification by TennCare and failure to comply with all of the requirements set forth in the manual may be cause for termination of this agreement and termination of the pharmacy provider's participation in the entire TennCare program.

**Unit Dose Dispensing:** Solid/liquid oral dosage forms provided to a long term care facility in unit of use packaging that bears the name of the drug, expiration date, control number, and name and address of the manufacturer. Unit dose dispensing is only reimbursable under this TennCare program when dispensed to a TennCare/Medicare enrollee who resides in a long term care facility (nursing home).

## SECTION 2 PROVISION OF PHARMACEUTICAL SERVICES

**Section 2.1: Provision of Pharmaceutical Services and Quality of Services.** Pharmacy shall provide Pharmaceutical Services to all TennCare enrollees in accordance with the standard of practice of the communities in which Pharmacy provides Pharmaceutical Services and in a manner so as to assure the quality of those services. TennCare will monitor the quality of services delivered under the Agreement and initiate corrective action where necessary to improve quality of care. Pharmacy shall provide Pharmaceutical Services without regard to race, religion, sex, color, national origin, age, or physical or mental health status. Pharmacy may not refuse to provide medically necessary or covered preventive services to a TennCare patient based upon non-medical reasons.

**Section 2.2: Compliance with Negative Drug Formulary, the TennCare PDL and TennCare Pharmacy Manual.** In providing any pharmaceutical service to a TennCare enrollee, Pharmacy shall comply with the Negative Drug Formulary to the extent the Negative Drug Formulary applies to such Pharmaceutical Service, unless Pharmacy is otherwise directed by TennCare. Beginning on July 1, 2003, Pharmacy will comply with the TennCare PDL and assist the TennCare Bureau in gaining PDL compliance from prescribers. Pharmacy agrees further that it shall at all times comply with the TennCare Pharmacy Manual in providing Pharmaceutical Services to TennCare enrollees.

**Section 2.3: Compliance With Policy On Unit Dose Drug Distribution.** In providing pharmaceutical services to a covered enrollee in a long term care facility (nursing home), pharmacy agrees to comply with TennCare program standards which include, but is not limited to, dispensing of a maximum 7-day supply of medication.

**Section 2.4: Collection of Co-Payments, Co-Insurance, Deductibles, and Ancillary Charges.**

Pharmacy shall collect any Co-payments, Co-Insurance Charges, Deductibles, Ancillary Charges, or other charges for Pharmaceutical Services provided by Pharmacy to TennCare members, as may be specified or required in the TennCare Pharmacy Manual and as required by TennCare. However, Pharmacy may not refuse to provide pharmacy services to TennCare members solely because the member is unable to pay a pharmacy co-payment, as required by federal law.

**Section 2.5: Utilization Management and Quality Assurance.** Pharmacy shall cooperate with all utilization review management, quality assurance, peer review, and other similar programs established by TennCare, including those performed by Contractors working for TennCare .

**Section 2.6: Payment for Zero Balance Claims.** TennCare requires that Pharmacy submit all claims for Pharmaceutical Services, even zero balance claims. This information is necessary for TennCare's Drug Utilization Review (DUR) activities and will be audited by TennCare periodically.

**Section 2.7: Submission of Claims.** Upon TennCare's request and as set forth in the TennCare Pharmacy Manual, Pharmacy shall submit all claims for Pharmaceutical Services provided under this Agreement via the TennCare POS on-line pharmacy claims processing system to TennCare for adjudication of such claims. All ambulatory pharmacy claims must be submitted via the online point-of-sale (POS) pharmacy claims processing system vendor contracted with the TennCare Bureau. Long term care pharmacy claims for eligible, TennCare/Medicare enrollees must be submitted via online or batch electronic claims media to the vendor contracted with the TennCare Bureau. Pharmacy claims may be submitted to TennCare up to three hundred sixty-five (365) days from the original date of service, unless otherwise approved by TennCare.

**Section 2.8: Non-Exclusivity.** This Agreement shall not prohibit any participating pharmacy from participating with any other third party payors.

**Section 2.9: 14-Day Supply.** Authorization of drugs, including prior approvals of non-preferred drugs and medical necessity reviews of non-preferred drugs, or denial of authorization of drugs shall be rendered by TennCare or its subcontractor within twenty-four (24) hours of the formal request for authorization. Upon determination that a prescription is not covered under the approved formulary or PDL, or the prescription requires a prior authorization that was not obtained, the Pharmacy will immediately attempt to contact the prescriber to offer PDL or formulary alternatives or assist the prescriber in obtaining authorization. If the prescriber cannot be reached in a timely fashion, or the prescriber insists that there are no acceptable PDL or formulary alternatives, or TennCare (or its agent) does not render a decision on the day of request, the Pharmacy must provide a 14-day emergency supply of the prescribed medication, provided that:

- (a) The medication is not a drug category specifically excluded from the TennCare formulary:

- Research drugs
- Medical supplies and durable medical equipment
- Injectables (except for in-home use administered by patient)
- Cough and cold products (except those listed in the OTC formulary)
- Biologicals
- Blood and blood plasma
- DESI, LTE, IRS drugs
- Nutritional and dietary supplements
- Most vitamins (see negative and OTC formularies)
- Antiobesity products

Topical minoxidil  
Anti-acne products  
Diagnostic products  
Cosmetic drugs  
Smoking Cessation products  
Fertility Drugs

- (b) The medication is not a drug in a non-covered TennCare therapeutic category (e.g., appetite suppressants, drugs to treat infertility); or
- (c) Use of the medication is not contraindicated because of the patient's medical condition or possible adverse drug interaction; or
- (d) If the patient is not already taking the medication, use of the medication for a fourteen day (14) period possibly followed by abrupt discontinuance of the drug would not be medically contraindicated; or
- (e) The prescriber did not prescribe a total quantity less than a fourteen (14) day supply, in which case the pharmacist must provide a supply up to the amount prescribed; or
- (f) Provision of the fourteen (14) day supply would not violate state or federal Controlled Substances Laws.

If the TennCare Bureau or its agent denies authorization of the drug requested and the prescriber insists there are no acceptable PDL or formulary alternatives or the enrollee wants the decision to be reconsidered, the Pharmacy and TennCare must provide the prescribed medication pending the conclusion of a grievance appeal to the Bureau of TennCare. A TennCare Drug Store Notice, explaining the patient's right to appeal must be given by the Pharmacy to the enrollee. The Pharmacy shall prominently display the notice of the fourteen-day (14) emergency supply policy at each service site. TennCare may, at its option, provide the language for the poster or will provide the posters, with personnel trained on the proper appeal procedures. Failure to provide a fourteen (14) day supply of the prescribed medication as described above or failure to post the notice may result in a material breach of the Participation Agreement and result in fines or termination of the agreement.

**Section 2.10: Credentialing/Reimbursement.** Pharmacy shall be obligated to participate in any and all TennCare pharmacy credentialing programs. Failure to participate in or successfully complete this program may result in termination of this agreement.

**Section 2.11: Professional or Technical Expertise.** Pharmacy shall be licensed in the jurisdictions in which it practices and shall employ only licensed pharmacists and shall satisfy the credentialing requirements of TennCare. Further, by agreeing to be bound by the Participation Agreement, Pharmacy assures that the functions and/or services it provides are within the scope of its pharmacists' professional/technical practice.

**Section 2.12: Adherence to TennCare Standards.** Pharmacy shall adhere to the TennCare Quality Standards as developed by TennCare.

### SECTION 3 PAYMENT FOR PHARMACEUTICAL SERVICES

**Section 3.1: Payment for Pharmaceutical Services.** TennCare shall pay Pharmacy in accordance with the TennCare Pharmacy Manual for Pharmaceutical Services provided by Pharmacy to a TennCare enrollee pursuant to a Prescriber's authorization. Reimbursement rates will vary depending on a type of provider basis (i.e. ambulatory or long term care). Ambulatory pharmacy claims will be reimbursed by paying the

lesser of: a) the provider's usual and customary charge to the general public; or b) A.W.P. minus 13% plus a \$2.50 dispensing fee; or c) MAC plus a \$2.50 dispensing fee. Long term care pharmacy claims will receive: a) A.W.P. minus 13% plus a \$5.00 dispensing fee if the days supply is equal to or greater than 28; or b) A.W.P. minus 13% plus a \$2.50 dispensing fee if the days supply is less than 28; or c) MAC plus a \$5.00 dispensing fee if the days supply is equal to or greater than 28; or d) MAC plus a \$2.50 dispensing fee if the days supply is less than 28; or e) the provider's usual and customary charge to the general public.

**Section 3.2: Obligation for Payment.** Obligation for payment under this Agreement for any Pharmaceutical Services rendered to a TennCare enrollee is solely that of TennCare. In no event shall TennCare be obligated to pay any claim from Pharmacy unless and until sufficient funds have been made available to TennCare.

**Section 3.3: Payment in Full.** Pharmacy shall accept as payment in full for Pharmaceutical Services rendered to TennCare enrollees such amounts as are established by this TennCare Agreement. In no event shall Pharmacy bill a TennCare enrollee for the difference between the Pharmacy's Usual and Customary Charge and the amount TennCare has agreed to reimburse the Pharmacy. Pharmacy may collect from a TennCare enrollee Co-payments, Co-insurance Charges, Deductibles or other charges for services not covered under the TennCare waiver.

**Section 3.4: TennCare enrollee Hold Harmless.** This section shall apply only to such TennCare enrollees as may be afforded the protection of this Section by applicable statutes or regulations. To the extent this Section conflicts with any other provisions of this Agreement, including, without limitation, Section 3.3, the terms and conditions of this Section shall apply. Pharmacy shall accept as payment in full for Pharmaceutical Services rendered to TennCare enrollees such amounts as are paid by TennCare pursuant to this Agreement. In no event, including, but not limited to, non-payment by TennCare for Pharmaceutical Services rendered to TennCare enrollees by Pharmacy, insolvency of TennCare, or breach by TennCare of any term or condition of this Agreement, shall Pharmacy bill, charge, collect a deposit from, seek compensation, remuneration or reimbursement from, or have any recourse against any TennCare enrollee or persons acting on behalf of the TennCare enrollee for Pharmaceutical Services eligible for reimbursement under this Agreement; provided, however, that Pharmacy may collect from the TennCare enrollee Co-payment, Co-insurance Charges, Deductibles or other charges for services not covered under the TennCare waiver. The provisions of this Section shall (a) apply to all Pharmaceutical Services rendered while this Agreement is in force; (b) with respect to Pharmaceutical Services rendered while this Agreement is in force, survive the termination of this Agreement regardless of the cause of termination; (c) be construed to be for the benefit of TennCare enrollees; and (d) supersede any oral or written agreement, existing or subsequently entered into, between Pharmacy and a TennCare enrollee or person acting on a TennCare enrollee's behalf, that required TennCare enrollee to pay for Pharmaceutical Services.

**Section 3.5: Prompt Payment:** Pharmacy shall promptly submit any and all information needed to make payment.

**Section 3.6: Time Period for Payment:** Upon receipt of a clean claim (into the POS pharmacy claims processing system) properly submitted by Pharmacy, TennCare shall pay Pharmacy within thirty (30) calendar days.

**Section 3.7: Acceptance of Surety and TennCare enrollees:** Pharmacy shall accept payment or appropriate denial made by TennCare as payment in full for covered services provided and shall not solicit or accept any surety or guarantee of payment from TennCare enrollees. TennCare enrollees shall include the patient, parent(s), guardian, spouse or any other legally responsible person of the patient being served.

**Section 3.8: TennCare Reimbursement:** Pharmacy shall be required to accept TennCare reimbursement amounts for services provided under the Participation Agreement between Pharmacy and TennCare to TennCare enrollees, and shall not be required to accept TennCare reimbursement amounts for services provided to persons who are covered by another health plan.

**Section 3.9: Non-covered therapeutic Drugs:** Under the TennCare Program, Pharmacy will be reimbursed for covered services if such services are medically necessary and on the TennCare PDL; provided, however, that non-covered therapeutic classes, (e.g., Appetite suppressants, drugs to treat infertility), DESI, LTE and IRS drugs shall be explicitly excluded. For these purposes, (a) “DESI” means Drug Efficacy Study and Implementation whereby drugs may be found to be LTE or IRS, (b) “LTE” means less than effective as determined by the Food and Drug Administration and (c) “IRS” means identical, related or similar to DESI or LTE. A partial listing of these DESI, LTE and IRS drugs may be found on the TennCare website ([www.tennessee.gov/tenncare](http://www.tennessee.gov/tenncare)).

Covered services under the Agreement shall include Early and Periodic Screening, Diagnosis and Treatment (“EPSDT”) services as medically necessary in accordance with 42 CFR Part 441 Subpart B and the Omnibus Budget Reconciliation Act of 1989 for children under the age of 21. Such screening shall be done in accordance with the periodicity schedule set forth in, and all components of this program shall be consistent with, the latest “American Academy of Pediatrics Recommendations for Preventative Pediatric Health Care.” Pharmacy shall make all treatment decisions under the Agreement with respect to children under the age of 21 based upon medical necessity in light of such child’s individual medical and behavioral health needs.

**Section 3.10: Generic Drugs:** The TennCare pharmacy program described in this agreement uses a maximum allowable cost (MAC) pricing system for multisource generic drugs. MAC prices for generic drugs will be published and available on the TennCare website at the following address: [www.tennessee.gov/tenncare](http://www.tennessee.gov/tenncare). When a pharmacy provider is presented a prescription for a brand name drug for a TennCare dual member (members with TennCare and Medicare) or for a brand name behavioral health prescription for a TennCare member and the prescriber has indicated on the face of the prescription to “dispense as written” (DAW), the pharmacist is required to do the following to assure compliance with the *Grier* Consent Decree and the TennCare Pharmacy Participation Agreement:

1. Contact the prescriber to see if the prescription may be changed to the generic form of the medication, *or*
2. If the prescriber is unwilling to change the prescription or if the prescriber is unavailable, dispense a 14-day supply of the brand name medication and give the member a “TennCare Drug Store Form” (appeal form).

If the brand name drug has a MAC (maximum allowable cost) price associated with its reimbursement, the pharmacist may either contact the TennCare Pharmacy Program at 1-888-816-1680 for override instructions or enter a DAW code of “1” (or the code designated by TennCare) in the appropriate NCPDP field.

If the prescriber does not request a DAW override or changes a prescription to the generic form of the medication and the member refuses the generic, still wanting the brand name version, then the pharmacist does not execute a DAW override and does not provide a 14-day supply of the brand name medication, yet still provides the member with an appeal form.

## SECTION 4 RELATIONSHIP BETWEEN PARTIES

**Section 4.1: Relationship Between TennCare and Pharmacy.** The relationship between TennCare and Pharmacy is that of independent contractors, and nothing in this Agreement or otherwise shall be construed or deemed to create any other relationship, including one of employment, agency, or joint venture.

**Section 4.2: Relationship Between Pharmacy and TennCare enrollees.** The relationship between Pharmacy and TennCare enrollees is that of pharmaceutical provider and patient. Nothing in this

Agreement shall be construed to require Pharmacy to provide any Pharmaceutical Service if in the Pharmacy's professional judgment such Pharmaceutical Service should not be provided.

**Section 4.3: Relationship Between Pharmacy and Long Term Care Facility.** The relationship between the pharmacy and the covered facility is that of an independent contractor. Nothing in this agreement or otherwise shall be considered or deemed to create a relationship between the TennCare and the long-term care facility.

**Section 4.4: Restrictions on Change in Relationship Between TennCare and Pharmacy:** To the extent required by TennCare, Pharmacy shall not enter into any subsequent agreements or subcontracts for any of the work contemplated under the Provider Agreement without approval of TennCare .

## **SECTION 5 LIABILITY INSURANCE AND INDEMNIFICATION**

**Section 5.1: Pharmacy Liability Insurance.** Participating pharmacies shall procure and maintain, at Pharmacy's sole expense, professional liability and malpractice insurance with limits of no less than One Million Dollars (\$1,000,000) for each claim and of no less than Three Million Dollars (\$3,000,000) aggregate, as well as comprehensive general liability insurance. Pharmacy shall also assure that all pharmacists and other health care professionals employed or under contract with Pharmacy to render Pharmaceutical Services to TennCare enrollees procure and maintain such insurance, unless they are covered under Pharmacy's insurance policies. Pharmacy's, pharmacists', and other health care professionals' professional liability insurance shall be either occurrence or claims made with an extended period reporting option under such terms and conditions as may be reasonably required by TennCare . Upon request by TennCare , Pharmacy shall submit to TennCare in writing evidence of insurance coverage. Pharmacy shall notify TennCare in writing, to the attention of the TennCare Pharmacy Director, fifteen (15) days prior to any denial of, restriction on, or termination of Pharmacy's general or professional liability insurance, except where such insurance is immediately replaced by equivalent insurance not subject to such denial, restriction, or termination. Pharmacy shall also notify TennCare, to the attention of the TennCare Pharmacy Director, within fifteen (15) days of any settlement or judgment that the Pharmacy is aware of adverse to Pharmacy which resulted from a malpractice complaint against Pharmacy.

**Section 5.2: Indemnification.** Pharmacy and TennCare each agree to indemnify and hold harmless the other party from any and all claims, liabilities, damages, or judgments imposed upon, incurred by or asserted against the other party which arise solely out of or derive solely from the negligence or fault of the first party.

## **SECTION 6 LAWS, REGULATIONS, AND LICENSES**

**Section 6.1: Laws, Regulations and Licenses.** Participating pharmacies shall maintain all federal, state, and local licenses, certifications, and permits, without restriction, required to provide Pharmaceutical Services to TennCare enrollees and shall comply fully with all applicable laws and regulations. Pharmacy shall notify TennCare in writing, to the attention of the TennCare Pharmacy Director, within ten (10) days of any suspension, revocation, condition, limitation, qualification, or other restriction of Pharmacy's license



by any state in which Pharmacy is authorized to provide Pharmaceutical Services which would prohibit Pharmacy from performing any of its obligations under this Agreement.

**Section 6.2: Exclusion from Participation in Government Health Care Programs.** Pharmacy shall immediately notify the TennCare Pharmacy Director of the exclusion of any pharmacist employed by the Pharmacy by the Office of Inspector General (OIG), the Department of Health and Human Services (HHS) or CMS. No pharmacists who have been excluded from participation in any government health care programs (Medicare, Medicaid, or other state or federal government health care programs) shall be permitted to participate in the TennCare program unless they can document that OIG, CMS or HHS has fully reinstated them as a participating provider. Pharmacy shall immediately notify TennCare if it has been excluded from participation in the Medicare and/or Medicaid programs pursuant to Sections 11.28 or 11.56 of the Social Security Act or is otherwise not in good standing with the TennCare Program. Failure to so notify TennCare shall constitute a material breach of the Agreement. Failure to provide TennCare with this information may also be cause for termination of the Pharmacy from participation in the TennCare program and recoupment of any and all reimbursements made to Pharmacy during the time period such excluded provider was providing Pharmaceutical Services to TennCare enrollees.

**Section 6.3: Compliance with Legal Regulations:** Both TennCare and Pharmacy agree to recognize and abide by all state and federal laws, regulations and guidelines applicable to the scope of services provided or anticipated to be provided by this Agreement, including the Tennessee state plan, 42 CFR 431.107, 42 CFR 455 subpart B, and Section 1200-13-1-.05(1)(a).

**Section 6.4: Incorporation by Reference of Federal and State Law/Regulation:** By reference, this agreement incorporates all applicable federal and state laws and regulations and any applicable court orders or consent decrees, and any and all revisions of such laws or regulations shall automatically be incorporated into the Participation Agreement as they become effective.

## **SECTION 7 SYMBOLS AND TRADEMARKS**

**Section 7.1: Use By Pharmacy.** Participating pharmacies shall have the right to designate and make oral or published reference to Pharmacy as a Participating Pharmacy; provided, however, that Pharmacy shall not otherwise use TennCare's name or its trademark for any advertising unless first approved in writing in advance by TennCare .

**Section 7.2: Use By TennCare .** TennCare shall have the right to designate and make oral or published reference to Pharmacy as a Participating Pharmacy; provided, however, that TennCare shall not otherwise use Pharmacy's name or its trademark for any advertising unless first approved in advance by Pharmacy.

## **SECTION 8 BOOKS AND RECORDS**

**Section 8.1: Access To and Release of Books and Records.** Subject to applicable confidentiality laws and regulations, during regular business hours and with or without notice and demand, TennCare shall have access to all information and records or copies of records maintained by Pharmacy related to Pharmaceutical Services provided by Pharmacy under this Agreement or related to analysis of the efficiency of healthcare management techniques by TennCare. Unless otherwise required by applicable laws or regulations, TennCare shall have such access at any time up to five (5) years following the date the Pharmaceutical Service was provided. Pharmacy shall provide records or copies of records requested by TennCare or their duly authorized agents within thirty (30) days from the date such request is made, or within shorter time [not less than fourteen (14) days] as may be required by applicable laws or regulations. Pursuant to Section 9, in the event of termination, Pharmacy shall immediately make available, to TennCare, or its designated representative, any or all records, whether medical, pharmacy, or financial,

related to the provider's activities undertaken pursuant to the Agreement. The provision of such records shall be at no expense to TennCare.

**Section 8.2: Compliance With Laws and Regulations.** The federal, state, and local governments and any of their authorized representatives shall have access to, and TennCare and Pharmacy are authorized to release, in accordance with applicable laws and regulations, all information and records, or copies of such, within the possession of TennCare or Pharmacy, which are pertinent to and involve transactions related to this Agreement and access to which is necessary to comply with laws and regulations applicable to TennCare.

**Section 8.3: Privacy of TennCare Enrollee's Records.** TennCare and Pharmacy shall maintain the confidentiality of all information regarding TennCare enrollees in accordance with any applicable state and federal laws and regulations, including the standards and requirements of HIPAA.

**Section 8.4: Confidential Business Information.** TennCare and Pharmacy shall take all necessary steps to provide maximum protection to the other party's trade secrets and other confidential business information, to the extent possible under state and federal law.

**Section 8.5: Confidentiality of Utilization Review Information.** Any records, data or other information imparted to Pharmacy or any of its employees in connection with utilization review panels established by TennCare shall be maintained as strictly confidential. Such information shall be used solely in the exercise of the proper functions of said panel(s). Pharmacy and its employees shall not disclose said information to any person, firm or entity, and shall notify TennCare immediately of any demand or request for any such information from any third party.

**Section 8.6: Maintenance of Medical Records-Access:** Pharmacy shall maintain an adequate record system for recording services, servicing Pharmacy, charges, dates and all other commonly accepted information elements for services rendered to TennCare enrollees pursuant to the participation agreement (including but not limited to such records as are necessary for the evaluation of the quality, appropriateness, and timeliness of services performed under Pharmacy Agreement). TennCare enrollees and their representatives shall be given access to their medical/pharmacy records, to the extent and in the manner provided by Tenn. Code Ann. §§63-2-101 and 63-2-102, and, be given copies thereof upon request.

**Section 8.7: Maintenance of Medical Records – Duration:** Pharmacy shall maintain any and all records for a period not less than five (5) years from the termination of the Participation Agreement and shall retain the records further if they are under review or audit until the review or audit is complete. Said records shall be made available for fiscal audit, medical audit, medical review, utilization review, and other periodic monitoring upon request of an authorized representative of TennCare.

**Section 8.8: Right to Inspection by Government Entities:** TennCare, the U.S. Department of Health and Human Services, and the Office of Inspector General Comptroller shall have the right to evaluate through inspection, whether announced or unannounced, or other means any records pertinent to the Participation Agreement including quality, appropriateness, and timeliness of services, and such evaluation, if performed, shall be performed with the cooperation of Pharmacy. Upon request, Pharmacy shall assist in such reviews including the provision of complete copies of pharmacy records.

**Section 8.9: Report Submission:** Pharmacy will submit all reports and clinical information required by TennCare .

**Section 8.10: Safeguarding Information:** Strict standards of confidentiality of records including, but not limited to, patient medical/pharmacy records and other similar records shall be maintained in accordance with all applicable state and federal laws and regulations.

**Section 8.11: Monitoring of Services Rendered:** Whether announced or unannounced, TennCare may monitor the services rendered to TennCare enrollees.

**Section 8.12: External Review:** Whether announced or unannounced, Pharmacy shall participate and cooperate in any internal and external quality review, audit, utilization review, peer review, Pharmacy and Therapeutics Committee Review, and appeal procedures established by TennCare.

## **SECTION 9 TERM AND TERMINATION**

**Section 9.1: Term.** Unless earlier terminated in the manner provided below, this Agreement shall be in effect commencing on the date first above written of the current year and shall continue thereafter for successive periods of twelve (12) months until terminated by either party upon written notice to the other party not less than sixty (60) days prior to the initial or any subsequent expiration date.

**Section 9.2: Termination by Pharmacy.** This Agreement may be terminated at any time by Pharmacy upon sixty (60) days written notice to TennCare.

**Section 9.3: Termination by TennCare.** This agreement may be terminated at any time by TennCare upon written notice to Pharmacy:

- (i) following written notice from TennCare that Pharmacy is in material breach of its obligations under this Agreement or any applicable agreement and the expiration, without cure of such material breach, of thirty (30) days after Pharmacy's receipt of such notice; or,
- (ii) in the event Pharmacy willfully refuses to provide Pharmaceutical Services to a TennCare enrollee, except as provided in Section 4.2; or,
- (iii) in the event Pharmacy's loss or suspension of licensure or loss of liability insurance required under this Agreement; or,
- (iv) following TennCare's receipt from Pharmacy of an objection to a proposed amendment to this Agreement pursuant to Section 10.1(b).: or,
- (v) the Pharmacy has been excluded from participation in the TennCare program by TennCare, a TennCare MCO, CMS, OIG or HHS; or,
- (vi) the Pharmacy has knowingly allowed a pharmacist who has been excluded from participation in the TennCare program by TennCare, a TennCare MCO, CMS, OIG or HHS to provide pharmaceutical services to TennCare enrollees; or,
- (vii) the Pharmacy has not complied with all of the emergency supply provisions contained in Section 2.9. above and any subsequent agreement amendments or revisions to court orders or consent decrees that pertain to the supply of emergency supply dispensings; or,
- (viii) the Pharmacy refuses to provide pharmacy services to a TennCare member solely because the member is unable to pay any or all pharmacy co-payments.

**Section 9.4: Continuation Provisions.** Pharmacy shall continue as a Participating Pharmacy under this Agreement during the notice period specified in Sections 9.2 and 9.3 unless otherwise notified by TennCare in writing of the suspension of all or part of its rights and obligations as a Participating Pharmacy. Upon termination of this Agreement, Pharmacy shall continue to perform the obligations of Participating Pharmacy under the Agreement in effect between TennCare and the Pharmacy at the time of termination which provide for continuation of such obligations, including those relating to continued provision of Pharmaceutical Services to TennCare enrollees, at the rates and for the period specified in such agreement, unless otherwise agreed by TennCare.

**Section 9.5: Application of Pharmacy.** It is the understanding of the parties that this Agreement shall be executed first by Pharmacy and upon such execution shall be an application by Pharmacy to become a party to this Agreement. As part of such application, Pharmacy shall complete the information in Exhibit A (Pharmacy Application). This signing of this Agreement by Pharmacy shall constitute an offer only, unless and until it is approved by TennCare in the State of Tennessee. This application by Pharmacy shall be

accepted by TennCare only if Pharmacy meets all participation criteria established by TennCare and only at TennCare's sole discretion.

**Section 9.6: *Grier* Revised Consent Decree Compliance.** Section 2.9 of this Agreement requires Pharmacy to comply with the 14-day emergency supply provisions of the *Grier* Revised Consent Decree. If the Pharmacy is found to be in violation of the *Grier* Revised Consent Decree, the Pharmacy may be warned and given corrective training, fined or the Agreement terminated. Violations may include, but not be limited to, failure to dispense a 14-day emergency supply of a non-preferred drug when appropriate, failure to provide a TennCare Drugstore Notice (appeal and patient rights form) when appropriate and failure to post any TennCare-required notices in the pharmacy area regarding the *Grier* Revised Consent Decree. The first violation identified by TennCare will result in counseling and training regarding the violation and compliance with the *Grier* Revised Consent Decree by Pharmacy. Pharmacy will be required to submit to TennCare, within ten (10) days, a written corrective action plan that demonstrates, in detail, the steps taken by Pharmacy to assure the violation will not be repeated. A second violation of the pharmacy provisions of the *Grier* Revised Consent Decree by Pharmacy may result in the imposition of monetary penalties (fines) up to one thousand five hundred dollars (\$1,500) per violation. Violations of the *Grier* Revised Consent Decree will result in Pharmacy's forfeiture of any incentive payments associated to PDL compliance and referred to in Section 10.11 of this Agreement. Repeated violations by Pharmacy may result in termination of the Agreement.

## **SECTION 10 MISCELLANEOUS**

**Section 10.1: Amendment.** This Agreement may be amended by TennCare. TennCare may amend this Agreement (a) to comply with applicable court orders, consent decrees, laws or regulations or (b) to affect any necessary policy changes by giving thirty (30) days written notice of an amendment to Pharmacy.

**Section 10.2: Assignment.** TennCare may assign all or any of its rights or responsibilities under this Agreement to any entity controlling, controlled by, or under common control with TennCare. Pharmacy acknowledges that persons and entities under contract with TennCare may perform certain administrative services under this Agreement. Pharmacy may not assign any of its rights or responsibilities under this Agreement to any person or entity without the prior written consent of TennCare, which consent shall not be unreasonably withheld.

**Section 10.3: Entire Agreement.** This Agreement, the Pharmacy Application and the Pharmacy Manual constitute the entire Agreement between the parties with respect to its subject matter.

**Section 10.4: Notices.** Any notice or other communication required or permitted under this Agreement shall be in writing. The notice or communication shall be deemed to have been given when delivered in person; or if delivered by United States mail, on the date mailed, proper postage prepaid and properly addressed to the address set forth next to the appropriate party's name at the end of this Agreement or to another more recent address of which the sending party has received written notice. Notices may also be sent via facsimile and through a web-based bulletin board process and e-mail and posted on TennCare's website.

**Section 10.5: Governing Law.** This Agreement shall be construed in accordance with all applicable laws of the State of Tennessee.

**Section 10.6: Indemnification – State of Tennessee:** Pharmacy agrees to indemnify and hold harmless the State of Tennessee as well as its officers, agents, and employees from and against any and all claims, liabilities, losses, and causes of action which may arise, accrue, or result to any person, firm, corporation or other entity which may be injured or damaged as a result of acts, omissions, bad faith, negligence, or willful misconduct on the part of the contractor, its employees, or any other person acting for or on its or

their behalf relating to this contract. Pharmacy further agrees that it shall be liable for the reasonable costs of attorneys for the State in the event such service is necessitated to enforce the terms of this contract or otherwise enforce the obligations of Pharmacy to the State. In the event of any such suit or claim, Pharmacy shall give the State immediate notice thereof and shall provide all assistance required by the State in the State's defense. The State shall give Pharmacy written notice of any such claim or suit and Pharmacy shall have the full right and obligation to conduct Pharmacy's own defense thereof. Nothing contained herein shall be deemed to accord to Pharmacy, through its attorney(s), the right to represent the State of Tennessee in any legal matter, such rights being governed by Tenn. Code. Ann. § 8-6-106.

**Section 10.7: Compliance with Appeals Process:** Pharmacy agrees to comply with the appeal process including but not limited to assisting a TennCare enrollee by providing appeal rights, appeal forms and contact information including the appropriate address for submitting appeals for state level review.

**Section 10.8: Displaying Notice of Appeal:** Pharmacy agrees to display notices of TennCare enrollee's right to appeal adverse decisions affecting services in public areas of their facility(ies) in accordance with TennCare Rule 1200-13-12-.11.

**Section 10.9: Conflict of Interest:** TennCare warrants that no part of this Agreement shall be paid directly or indirectly to any officer or employee of the State of Tennessee as wages, compensation, or gifts in exchange for acting as an officer, agent, employee, subcontractor, or consultant to TennCare in connection with any work contemplated or performed relative to this Agreement unless otherwise authorized by the Commissioner, Tennessee Department of Finance & Administration.

**Section 10.10: Fraud Investigations:** Pharmacy shall immediately report to the TennCare Pharmacy Director or the Tennessee Bureau of Investigation Medicaid Fraud Control Unit ("TBI MFCU") any suspicion or knowledge of fraud and/or abuse, including but not limited to the false or fraudulent filings of claims and/or the acceptance or failure to return monies allowed or paid on claims known to be false, incorrect, inaccurate or fraudulent. The reporting entity shall not attempt to investigate or resolve the reported suspicion, knowledge or action without informing the TennCare Pharmacy Director or the TBI MFCU and must cooperate fully in any investigation by the TennCare Pharmacy Director or the TBI MFCU or subsequent legal action that may result from such an investigation. Pharmacy, shall, upon request, make available to the TennCare Pharmacy Director or the TBI MFCU any and all administrative, financial and medical records relating to the delivery of items or services for which TennCare monies are expended. Additionally, the TennCare Pharmacy Director or the TBI MFCU shall be allowed access to place of business and to all records of the Pharmacy, during normal business hours, except under special circumstances when after-hour admission shall be allowed. Special circumstances shall be determined by the TennCare Pharmacy Director or the TBI MFCU.

**Section 10.11: Participating Pharmacy Provider Incentive Payments:** On or after July 1, 2003, TennCare will implement a single, statewide preferred drug list (PDL) that will define the pharmacy benefit for all TennCare members. Participating pharmacy providers will submit all TennCare pharmacy claims to the TennCare PBM for adjudication. Participating pharmacy providers are required to contact the prescriber in the event a TennCare member presents a prescription for a non-preferred or non-covered drug and request or suggest a covered alternative medication to replace the original (non-covered) prescription. After implementation of the first three phases of the PDL, TennCare will review pharmacy claims data every six months to analyze every participating pharmacy provider's compliance with the PDL. In the event a participating pharmacy provider maintains a ninety percent or greater PDL compliance rate for that six month time period, the participating pharmacy provider will be paid ten cents (\$0.10) for every TennCare prescription that participating pharmacy provider dispensed during that six-month time period. If any participating pharmacy provider is found to have violated the *Grier* Revised Consent Decree during that six-month time period, however, that participating pharmacy provider will forfeit all incentive payments for the period and be subject to the sanctions described in Section 9.6 above.

**Section 10.12: Debarment and Suspension.**

To the best of its knowledge and belief, the Pharmacy certifies by its signature to this Agreement that the Pharmacy and its principals:

- (a) are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from covered transactions by any federal or State department or Pharmacy;
- (b) have not within a three (3) year period preceding this Agreement been convicted of, or had a civil judgment rendered against them from commission of fraud, or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (federal, State, or Local) transaction or grant under a public transaction; violation of federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification, or destruction of records, making false statements, or receiving stolen property;
- (c) are not presently indicted for or otherwise criminally or civilly charged by a government entity (federal, State, or Local) with commission of any of the offenses detailed in section b. of this certification; and
- (d) have not within a three (3) year period preceding this Agreement had one or more public transactions (federal, State, or Local) terminated for cause or default.

The Pharmacy's signature on the Agreement shall serve as certification of compliance with this policy. If any doubt exists, officials may check a list maintained by the General Services Administration which lists persons who have been debarred, suspended or proposed for debarment under 45 CFR Part 76 or 48 CFR Part 9, Subpart 9.4. The list can be found at: <http://epls.arnet.gov/>

If a person is debarred, suspended or proposed for debarment during the term of the Agreement or if the State determines that an agency has misrepresented its status, a decision as to the type of termination action, if any, will be made after a thorough review to ensure the propriety of the proposed action. In this event, the Agreement will not be renewed or extended (other than no-cost time extensions).

Pharmacy has read the TennCare Pharmacy Manual, completed the Pharmacy Application, executed and delivered this offer the date written below:

Pharmacy: \_\_\_\_\_

Address: \_\_\_\_\_

By (signature)\_\_\_\_\_

Print Name: \_\_\_\_\_

Print Title: \_\_\_\_\_

\_\_\_\_\_

Date: \_\_\_\_\_

**Return this fully completed signature page and all required application forms to:**

**TennCare**

**Attn: Pharmacy Program**

**729 Church Street**

**Nashville, Tennessee 37247-6501**

**Or fax it to: TennCare toll-free 1-888-298-4130**